

REMARKS

The Office Action dated March 31, 2010 has been received and reviewed. Claims 1 to 40 are pending in the application. Claims 1-20, 27-32 and 35-39 are rejected. Claims 21-26, 33, 34 and 40 are withdrawn.

Claim 1 is currently amended to include the features of claim 7, which is currently canceled.

Claim 8 is currently amended to depend from claim 1. This amendment is supported by the original claims because claim 8 originally depended from claim 7, which features are currently incorporated into claim 1.

Claim 17 is currently canceled.

Claim 18 is currently amended to include the features of claim 19, which is currently canceled.

Claim 27 is currently amended to include the features of claim 32, which is currently canceled.

Reexamination of the claims is respectfully requested.

Rejections under 35 USC 102

Claims 1-9 and 11-17 are rejected under 35 USC 102(b) as being anticipated by Buechler (US 6,156,270). Claim 1 is currently amended to include the features of claim 7, which is hereby cancelled. The Patent Office asserts that all of the features of claim 7 are disclosed by Buechler. Applicant respectfully disagrees.

The following excerpt¹ shows the Patent Office's analysis of the Buechler document:

Buechler teaches a detection cartridge comprising a housing (9) comprising an interior volume, a sensor operably attached to the housing, refer to Col. 7, lines 4-7, the sensor comprising a detection surface. It is inherent that that acousto-mechanical sensor has a detection surface and it must be attached to the device of Buechler. Buechler further teaches a detection chamber (6) located within the interior volume of the housing (9). The detection chamber (6) comprises a volume defined by the detection surface and an opposing surface spaced apart from and facing the detection surface, wherein the opposing surface comprises a flow front control feature (grooves). (Refer to Figure 1) Buechler further teaches a waste chamber (7) located within the interior volume of the housing (9), the waste chamber in fluid communication with the detection chamber (6). (Refer to Figure 1) According to Col. 7, Lines 4-7, the detection surface comprises an acousto-mechanical waveguide and a surface acoustic wave acousto-mechanical sensor. According to Figures I -1A, the flow front control feature (grooves)

¹ Office Action dated 03/31/2010 at page 3.

comprises discrete structures protruding from and separated by a land area on the opposing surface of the detection chamber and the flow front control feature (grooves) comprises one or more channels in the opposing surface of detection chamber (6). According to Figure 1, at least one channel of the one or more channels is oriented generally perpendicular to a longitudinal axis defined within the detection chamber (6) between an input end and an output end of the waste chamber (7). The flow front control feature (groove) comprises one or more regions of hydrophobic material occupying a portion of the opposing surface and one or more regions of hydrophilic material occupying a portion of the opposing surface. (Refer to Col. 5, Lines 40-50) Buechler further teaches at least one pair of successive bands of hydrophobic material and hydrophilic material wherein each pair of successive bands extends across a width of the detection chamber (6). (Refer to Col. 5, Lines 40-50 and Figure 1) Buechler further teaches the cartridge further comprises capillary structure, refer to figure 2, located between the detection chamber (6) and the waste chamber (7). Buechler further teaches a vent, refer to col. 4, line 37, that, when open, places the interior volume of the housing in fluid communication with ambient atmosphere around the cartridge. Buechler further teaches the vent comprises a closure element (64). (Refer to Col. 36, Lines 1-6)

In its argument, the Patent Office appears to equate the grooves (in the detection chamber 6 shown in Figure 1-1A) with the flow front control feature of claim 1.

The dispute is not whether Buechler discloses a reaction chamber, grooves, hydrophobic surfaces and hydrophilic surfaces. Rather, the dispute is whether Buechler teaches or suggests the whole invention of amended claim 1.

Amended claim 1 includes a detection chamber with a volume defined by a detection surface and an *opposing surface* spaced apart from and facing the detection surface. The opposing surface includes a flow front control feature that includes one or more regions of hydrophobic material occupying a portion of the opposing surface and one or more regions of hydrophilic material occupying a portion of the opposing surface.

Although Buechler discloses assay devices comprising “two opposing surfaces disposed a capillary distance apart”², there is very little discussion regarding the nature and properties of the surface that opposes the detection surface (diagnostic element 6). In one of the references to the “opposing surface”, Buechler discloses that the opposing surface “can be hydrophobic or hydrophilic in nature and smooth, grooved, or textured.”³ Applicant notes that, in the cited passage, Buechler does not disclose that the opposing surface may be *both* hydrophobic and hydrophilic.

² U.S. Patent No. 6,156,270; at column 3, lines 61-62.

³ *Ibid*, column 11, lines 45-46.

In a further reference to the opposing surface, Buechler strongly suggests that the use of a hydrophobic material results in improved performance of the diagnostic device:

“In a preferred embodiment the surface opposing the diagnostic element 6 is hydrophobic such that the reaction mixture repels this surface. The repulsion of reaction mixture to the surface opposing the diagnostic element 6 forces the reaction mixture, and particularly the protein conjugates, to the surface where capture occurs, thus improving the capture efficiency of the components of the reaction mixture to the capture zone.”⁴

Accordingly, it can be concluded that Buechler teaches away from using hydrophobic and hydrophilic regions in the opposing surface because it could be reasonably inferred that the use of hydrophilic materials in the opposing surface would lead to diminished performance of the device (i.e., decreased capture efficiency).

In summary, amended claim 1 is patentable over Buechler because Buechler does not teach or suggest a detection cartridge comprising a detection chamber with an opposing surface that includes a flow front control feature comprising one or more regions of hydrophobic material occupying a portion of the opposing surface and one or more regions of hydrophilic material occupying a portion of the opposing surface. Claims 2-6, 8-9, and 11-16 each add additional features to amended claim 1 and are likewise patentable over Buechler. Withdrawal of the rejection of claims 1-6, 8-9, and 11-16 under 35 USC 102(b) as being anticipated by Buechler (US 6,156,270) is respectfully requested.

Claims 27-32 and 35-39 are rejected under 35 USC 102(b) as being anticipated by Wiegner (US 4,013,722).

Claims 27 is currently amended to include the features of claim 31, which is currently canceled. Amended claim 27 is drawn to a sealed module wherein the liquid in the first chamber comprises a water and the reagent in the second chamber comprises a hydrolyzable material. In the arguments (copied below) provided by the Patent Office to support the rejection of claims 27-32 and 35-39 under 35 USC 102(b) as being anticipated by Wiegner, the Patent Office does not assert that Wiegner discloses a sealed module wherein the liquid in the first chamber comprises a water and the reagent in the second chamber comprises a hydrolyzable material.

“Wiegner teaches a housing (2) comprising an exit port and a sealed interior volume, refer to figure 1, an exit seal located over the exit port (4), a first chamber (11) located within the interior volume of the housing

⁴ *Ibid*, column 17, lines 17-24.

(2), the first chamber comprising a liquid located therein, refer to Figure 1, a second chamber (1) located within the interior volume of the housing (2), the second chamber comprising a reagent located therein, refer to Figure 1, an inter-chamber seal (7) isolating the second chamber from the first chamber within the housing (2) and a plunger (6), wherein the first chamber, the interchamber seal, the second chamber, and the exit seal are located between the plunger and the exit port. (Refer to Figure 1) The plunger (6) is movable from a loaded position in which the plunger is distal from the exit port to an unloaded position in which the plunger is proximate the exit port. The movement of the plunger (6) towards the exit port (4) opens the inter-chamber seal (7) such that the liquid in the first chamber contacts the reagent in the second chamber and the unloaded position opens the exit seal such that the liquid and the reagent from the interior volume of the housing exit through the exit port (4). The plunger (6) comprises a tip, refer to Figure 1, wherein the tip faces the inter-chamber seal and wherein the tip pierces the inter-chamber seal to open the inter-chamber seal.”⁵

Because the Patent Office fails to assert that Wiegner discloses all of the elements of amended claim 27, the Patent Office has not established prima facie that amended claim 27 is anticipated by Wiegner. Therefore, amended claim 27 is patentable over Wiegner. Claims 28-30 and 32 each add additional features to claim 27 and are likewise patentable over Wiegner.

In the passage cited above, the Patent Office further does not appear to assert that Wiegner discloses the “input port” of claim 35. Because the Patent Office fails to assert that Wiegner discloses all of the elements of claim 35, the Patent Office has not established prima facie that claim 35 is anticipated by Wiegner. Therefore, claim 35 is patentable over Wiegner. Claims 36-39 each add additional features to claim 35 and are likewise patentable over Wiegner.

In summary, the Patent Office has not established prima facie that pending claims 27-30, 32, and 35-39 are anticipated by Wiegner. Withdrawal of the rejection of claims 27-30, 32, and 35-39 under 35 USC 102(b) as being anticipated by Wiegner (US 4,013,722) is respectfully requested.

Rejection under 35 USC 103

Claim 10 is rejected under 35 USC 103(a) as being unpatentable over Buechler.

Amended claim 1 is patentable over Buechler for at least the reasons discussed above. Claim 10 is dependent to amended claim 1. Because the Patent Office does not rely on any disclosure other than Buechler, claim 10 is likewise patentable over Buechler.

⁵ Office Action dated 03/31/2010 at pages 7-8.

Withdrawal of the rejection of claim 10 under 35 USC 103(a) as being unpatentable over Buechler is respectfully requested.

Claims 18-20 are rejected under 35 USC 103(a) as being unpatentable over Buechler in view of Wiegner (US 4,103,772).

Claim 18 is currently amended to include the features of claim 19. Amended claim 18 is drawn to a detection chamber comprising a staging chamber within the interior volume of the cartridge housing, wherein the staging chamber is located upstream from the detection chamber, and wherein the module ports open into the staging chamber. In the arguments (copied below) provided by the Patent Office to support the rejection of claims 18-20 under 35 USC 103(a) as being unpatentable over Buechler in view of Wiegner (US 4,103,772), the Patent Office does not assert that either Buechler or Wiegner disclose a detection chamber comprising a staging chamber within the interior volume of the cartridge housing, wherein the staging chamber is located upstream from the detection chamber, and wherein the module ports open into the staging chamber. Please note that the Patent Office's analysis of the Buechler document is copied above.

Refer above for the teachings of Buechler.

Buechler fails to teach one or more sealed modules, wherein each module of the one or more sealed modules comprises an exit port attached to the cartridge housing through one or more module ports that open into the interior volume of the cartridge housing, and wherein each module further comprises: a module housing comprising an exit port and a sealed interior volume, an exit seal located over the exit port of the module; and a plunger located within the interior volume of the module housing, wherein the plunger is movable from a loaded position in which the plunger is distal from the exit port to an unloaded position in which the plunger is proximate the exit port; wherein movement of the plunger towards the exit port opens the exit seal such that material from the interior volume of the module housing exits through the exit port into the interior volume of the cartridge housing.

Wiegner teaches disposable container comprising a module housing comprising an exit port and a sealed interior volume, an exit seal located over the exit port of the module; and a plunger (6) located within the interior volume of the module housing (2), wherein the plunger is movable from a loaded position in which the plunger is distal from the exit port to an unloaded position in which the plunger is proximate the exit port; wherein movement of the plunger towards the exit port opens the exit seal such that material from the interior volume of the module housing exits through the exit port into the interior volume of the cartridge housing. (Refer to Figure 1)

It would have been obvious to one having ordinary skill in the art to provide the device of Buechler with the container of Wiegner in order to ensure

no contamination of sample when introducing the sample to the sample addition zone of Buechler.

Therefore, the Patent Office has not established *prima facie* that the modification of Buechler with Wiegner can result in the detection chamber of amended claim 18.

MPEP 706.02(j) states, “It is important for an examiner to properly communicate the basis for a rejection so that the issues can be identified early and the applicant can be given fair opportunity to reply”. The Patent Office has not properly communicated the basis for the rejection of original claim 19. Clarification is requested.

In summary, amended claim 18 is patentable over Buechler in view of Wiegner because the Patent Office has not met the burden of establishing a *prima facie* argument of unpatentability. Claim 20 adds additional features to claim 18 and is likewise patentable over Buechler in view of Wiegner. Withdrawal of the rejection of claims 18 and 20 under 35 USC 103(a) as being unpatentable over Buechler in view of Wiegner (US 4,103,772) is respectfully requested.

All outstanding objections and rejections are believed to have been met and overcome. If a telephonic conference with Applicants' undersigned representative would be useful in advancing the prosecution of the present application, the Examiner is invited to contact the undersigned at (651) 736-7430. A notice of allowance for all pending claims is respectfully solicited.

Respectfully submitted,

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